

| Notice of Allowability | Application No. | Applicant(s) | |
|-------------------------------|------------------------|---------------------|--|
| | 09/555,629 | YAMAZAKI ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to the amendment of 19 October 2004.
2. The allowed claim(s) is/are 6 (renumbered as claim 1).
3. The drawings filed on 31 July 2001 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) hereto or 2) to Paper No./Mail Date _____.
 - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
Paper No./Mail Date _____
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristi Rupert on 10 November 2004.

The application has been amended as follows:

In claim 6, line 4: Delete "creatine" and insert therefore --creatinine--

Informal Examiner's Amendment

Applicant is advised that the title of the invention has been amended to more accurately reflect the invention recited in the claims. The new title is "METHOD FOR TREATMENT OF RENAL FAILURE BY CONTINUOUS ADMINISTRATION OF HEPATOCYTE GROWTH FACTOR".

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance:

The claimed method for treating renal failure comprising administering an effective amount of hepatocyte growth factor by continuous administration is novel and nonobvious. The prior art teaches intravenous administration of HGF to mice with acute renal failure (Kawaida et al. Proc Natl Acad Sci USA 91: 4357-4361, 1994). The prior art also teaches continuous

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administration of HGF to *normal* Sprague-Dawley rats (Ha-Kawa et al. Jpn Pharmacol Ther 24: 149-152, 1996). However, there is no motivation to combine the references because the intravenous administration of HGF as taught by Kawaida et al. results in suppressed BUN and creatinine levels and renal regeneration, with no disclosed side effects or problems with the treatment. It is noted that Applicant has the right to file divisional or continuation applications to protect the inventions in the cancelled claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
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10 November 2004

